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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,026	10/02/2006	Frans-Josef Meyer-Almes	BHC 03 1002	5952

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EXAMINER	
TURK, NEIL N	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,026	MEYER-ALMES ET AL.	
	Examiner	Art Unit	
	NEIL TURK	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☒ Claim(s) *2, 4, and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 recites that the molecule is an organic or inorganic molecule. Such a recitation does not further limit the molecule of claim 1 as there are no other possibilities outside of the molecule being organic or inorganic.

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 recites that the fluorescent dye is covalently or non-covalently coupled to the molecule, and such a recitation does not properly further limit claim 1 as there are no other possibilities outside of covalently and non-covalently. The recitation of claim 4 which recites, "...and optionally..." does not cure the deficiency to properly further limit claim 1 as the recitation is optional.

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 recites that the organic molecule is a peptide or peptidomimetic. This recitation does not properly further limit claim 2, as claim 2 recites an "or" in which an organic molecule is not necessarily chosen (not required) in claim 2.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what steps are involved in the method. The preamble of claims 1-7 and 9 recite "a method of homogenously, directly and quantitatively measuring molecule modifications", however the body of the claims does not present any active steps involved in such a method. Claim 1 does not recite any active method steps and instead appears to be claiming a fluorescent dye on a molecule and the molecule alone has a different fluorescent lifetime than the combination of fluorescent dye and molecule. These limitations are not drawn to an active method, but appear to intend to recite a composition of a particular fluorescent dye and a particular molecule. Applicant should recite the active steps involved in

"homogenously, directly and quantitatively measuring molecule modifications" so as to clearly define the intended method. Examiner also notes that dependent claims 2-7 and 9 do not recite any active steps involve in the method. As such, prior art which discloses a molecule with a fluorescent dye in which the fluorescent lifetime of such a combination is different from that of the molecule alone will be said to read on the claimed method of claim 1. Likewise in the dependent claims 2-9, prior art will only need to recite the further positively recited elements as no method steps have been claimed. For example, claim 5 recites, "...for quantifying biochemical assays". Are there additional method steps intended to be recited in claim 5 that provide for quantifying biochemical assays or is the recitation of claim 5 merely an intended use limitation of the method of claim 1? As currently recited, the limitation of claim 5 is drawn to an intended use limitation. This is likewise seen in claim 7, which currently merely recites an intended use limitation.

Claim 1 recites the limitations "the molecule", "the fluorescent lifetime", "the modified molecule". There is insufficient antecedent basis for this limitation in the claim.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how enzymes and the modification reactions they can carry out relate to the method of claims 1 and 5. Enzymes have not been claimed as a positive element in the claims and further limitations thereto are not clearly defined in the claims. Thereby, prior art which discloses the positively recited elements of

claims 1 and 5 will be said to read on the limitations of claim 6 as all of the necessary recited elements will have been disclosed by the prior art and such prior art will be said to be capable of having enzymes capable of carrying out the recited modification reactions.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what fluorescent dye-molecule conjugates and other reagents are included in the kit. It is unclear which such conjugates and "other reagents" are *required* for carrying out the assay method of claims 1 to 6. Claim 8 provides an undefined kit as there is no way of telling what fluorescent dye-molecule conjugates and other reagents are required for carrying out the assay method of claims 1 to 6, as the method of claims 1 to 6 is unclearly defined in such respect. What are the required fluorescent dye-molecule conjugates and other reagents in the kit so as to carry out the method of claims 1 to 6? As currently recited, prior art which discloses a reagent kit for carrying out the inventive method of the prior art will be said to read on the kit of claim 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kask (US 2002/0063863), hereafter Kask.

Kask discloses homogenous drug screening methods using fluorescently labeled samples for identifying protein ligands (e.g. calmodulin), whose fluorescence lifetime is influenced by protein-peptide interaction. Kask discloses fluorescence lifetime analysis is used as a measurement method for the analysis (abstract, [0009]+). Kask discloses examples of fluorescently labeled peptides in paragraphs [0080-0084], which include fluorescent dyes such as Cyanine 5 for labeling the peptide (the labeled peptide has a different fluorescent liftetime than the peptide alone so as to allow for measurement by fluorescent liftetime analysis). Examiner notes that the limitations of claims 5 and 7 do not recited additional steps to the method of claim 1 and are recited as intended use limitations. Further, Kask discloses such limitations as the limitations of claim 5 are disclosed in the example of the Calmodulin-Peptide interaction ([0080-0090, 0093+], tables 1-3; figs. 1-6), and Kask discloses that the methods of the disclosure are suited for performing high throughput screening assays ([0057]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kask in view of Giuliano et al. (6,416,959), Hereafter Giuliano.

Kask has been discussed above.

Kask does not specifically disclose a reagent kit for carrying out the method.

Giuliano discloses systems, methods, screens, reagents, and kits for optical system analysis of cells to rapidly determine the distribution, environment, or activity of fluorescently labeled reporter molecules in cells for the purpose of screening large numbers of compounds (abstract+).

It would have been obvious to modify Kask to include a kit with the necessary fluorescent dye-molecules and reagents such that Giuliano discloses that it is known to provide the necessary reagents in a tangible form, as a kit, so as to carry out the inventive method for the practical purpose of screening large numbers of compounds (practical purpose in Kask would also be for high throughput screening), and providing the required elements in a kit is thereby an obvious modification to provide a marketable and tangible medium for carrying out the inventive method of Kask.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797